

## Technology Appraisal Committee Meeting (Committee D)

**Minutes:** **Confirmed**

**Date and Time:** Tuesday 3 February 2015, 10am to 5pm

**Venue:** National Institute for Health and Care Excellence  
Level 1A, City Tower  
Piccadilly Plaza  
Manchester  
M1 4BT

<b>Present:</b>	1. Professor Gary McVeigh, Chair 2. Dr Lindsay Smith, Vice Chair 3. Dr Aomesh Bhatt 4. Dr Matthew Bradley 5. Dr Ian Campbell 6. Dr Ian Davidson 7. Professor Simon Dixon 8. Dr Alexander Dyker 9. Mrs Gillian Ells 10. Dr Susan Griffin 11. Professor Carol Haigh 12. Professor John Henderson 13. Professor John Hutton 14. Professor Steven Julious 15. Mr Malcolm Oswald 16. Professor Femi Oyebode 17. Dr Mohit Sharma 18. Dr Murray Smith	Present for all notes Present for all notes Present for notes 10 to 27 Present for all notes Present for notes 1 to 25 Present for all notes Present for all notes
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### **In attendance:**

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Martyn Burke	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Professor Matthew Cramp	Consultant Hepatologist, clinical expert nominated by Gilead	Present for notes 1 to 17
Dr Melinda Goodall	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 1 to 17
Mr Charles Gore	Chief Executive, the	Present for notes 1 to 17

Dr Helen Harris	Hepatitis C Trust, patient expert nominated by the Hepatitis C Trust	Present for notes 1 to 17
Helen Knight	Clinical Scientist, clinical expert nominated by Public Health England	Present for all notes
	Associate Director, National Institute for Health and Care Excellence	
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Dr Emma Simpson	Research Fellow, School of Health and Related Research (ScHARR)	Present for notes 1 to 17
Dr Paul Tappenden	Senior Research Fellow, School of Health and Related Research (ScHARR)	Present for notes 1 to 17
Dr Praveen Thokala	Research Fellow, School of Health and Related Research (ScHARR)	Present for notes 1 to 17
Ian Watson	Technical Analyst, National Institute for Health and Clinical Excellence	Present for notes 18 to 27

#### **Non-public observers:**

Ms Tara Finn	Work placement, National Institute for Health and Clinical Excellence	Present for notes 1 to 17
Mr Joost de Folter	Operational Researcher, National Institute for Health and Care Excellence	Present for notes 1 to 27
Ms Abigail Stevenson	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17

#### **Notes**

#### **Welcome**

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of ledipasvir-sofosbuvir for treating chronic hepatitis C and ustekinumab for treating active psoriatic arthritis (Rapid Review of TA133).

2. The Chair informed the Committee of the non-public observers at this meeting: Ms Tara Finn, Mr Joost de Folter, Ms Abigail Stevenson
3. Apologies were received from Dr Andrew Black, Professor David Bowen, Mrs Tracey Cole, Mrs Susan Dutton, Professor Paula Ghaneh, Dr Tim Kinnaird and Dr Warren Linley

## **Any other Business**

4. None

## **Appraisal of ledipasvir-sofosbuvir for treating chronic hepatitis C**

### **Part 1 – Open session**

5. The Chair welcomed the invited experts: Professor Matthew Cramp, Mr Charles Gore, Dr Helen Harris, Dr Emma Simpson, Dr Paul Tappenden and Dr Praveen Thokala to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Gilead to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Dr Aomesh Bhatt, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Professor Simon Dixon, Dr Alexander Dyker, Mrs Gillian Ells, Dr Susan Griffin, Professor Carol Haigh, Professor John Hutton, Professor Steven Julious, Professor Gary McVeigh, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of ledipasvir-sofosbuvir for treating chronic hepatitis C.
  - 7.2. Professor John Henderson declared a non-personal non-specific pecuniary interest. Professor Henderson participated in a trial of a drug manufactured by one of the comparator companies, but withdrew prior to recruitment. He received expenses, but has no other financial gains from the study.
    - 7.2.1. It was agreed that this declaration would not prevent Professor John Henderson from participating in this section of the meeting
  - 7.3. Professor Carolyn Young was absent from the meeting due to declaring a personal non-specific pecuniary interest due to receiving honoraria for teaching from one of the comparator companies.
8. The Chair asked all NICE Staff to declare any relevant interests.
  - 8.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of ledipasvir-sofosbuvir for treating chronic hepatitis C.

9. The Chair asked all other invited guests to declare their relevant interests.
  - 9.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of ledipasvir-sofosbuvir for treating chronic hepatitis C.
10. The Chair introduced the lead team, Dr Susan Griffin, Professor John Henderson and Mr Malcolm Oswald who gave presentations on the clinical effectiveness and cost effectiveness of ledipasvir-sofosbuvir for treating chronic hepatitis C.
11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of ledipasvir-sofosbuvir for treating chronic hepatitis C on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
  - 11.1. The nature of the condition, and how chronic hepatitis C affects the quality of life of patients.
  - 11.2. The clinical management of chronic hepatitis C.
  - 11.3. The marketing authorisation of ledipasvir-sofosbuvir and the recommended treatment duration.
  - 11.4. The clinical effectiveness evidence including:
    - the design of clinical trials available for ledipasvir-sofosbuvir
    - the clinical effectiveness evidence available for people with HCV genotype 1, 3 and 4
    - the generalisability of the clinical effectiveness evidence
    - whether a mixed treatment comparison was appropriate
  - 11.5. The cost effectiveness evidence including:
    - the selection of SVR rates for comparators
    - the omission of relevant health effects from the company's model (onward transmission, re-infection)
    - the baseline characteristics of the population, transition probabilities and the utility values included in the company's economic model
  - 11.6. The evidence submitted for people co-infected with HIV, or after transplantation and whether the Committee was able to make recommendations for these populations.
  - 11.7. Whether its preliminary recommendations were fair and constituted an equality issue for people with HCV genotype 4.
12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
13. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
14. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Committee continued to discuss the clinical and cost effectiveness of ledipasvir-sofosbuvir for treating chronic hepatitis C.
17. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Appraisal of Ustekinumab for treating active psoriatic arthritis (Rapid Review of TA313)**

### **Part 1 – Open session**

18. The Chair welcomed company representatives from Janssen to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
  - 19.1. Dr Aomesh Bhatt, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Professor Simon Dixon, Dr Alexander Dyker, Mrs Gillian Ells, Dr Susan Griffin, Professor Carol Haigh, Professor John Henderson, Professor John Hutton, Professor Steven Julious, Professor Gary McVeigh, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Ustekinumab for treating active psoriatic arthritis (Rapid Review of TA313).
  - 19.2. Professor Simon Dixon declared a non-personal non-specific non-pecuniary interest. Professor Dixon is a director of a health Economics unit who have undertaken work from two of the comparator companies. Neither pieces of work were related to this topic or drugs, nor was Professor Dixon personally paid for the work.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
  - 19.3. Professor Steven Julious declared a personal non-pecuniary non-specific interest. Professor Julious was a member of a monitoring committee for one of the comparator companies but did not receive any payment personally.
    - 9.3.1 It was agreed that this declaration would not prevent Professor Steven Julious from participating in this section of the meeting.
  - 19.4. Professor Carolyn Young was absent from the meeting due to declaring a personal non-specific pecuniary interest. Professor Young is the principal investigator for a comparator company's study and has received payment for this work.
20. The Chair asked all NICE Staff to declare any relevant interests.

- 20.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Ustekinumab for treating active psoriatic arthritis (Rapid Review of TA313).
21. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Ustekinumab for treating active psoriatic arthritis (Rapid Review of TA313) on the basis of the evidence before them. The discussions included:
  - 21.1. Comments received from consultees and commentators on the Appraisal Consultation Document (ACD)
  - 21.2. Issues arising that could affect the Committee's preliminary recommendations, and whether any changes to those recommendations were needed
22. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
23. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
24. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

25. The Committee continued to discuss the clinical and cost effectiveness of Ustekinumab for treating active psoriatic arthritis (Rapid Review of TA313).
26. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

## **Date, time and venue of the next meeting**

27. Wednesday 4 March 2015, 10am to 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.